BIOMET MANUFACTURING CORP.

MAR 2 8 2013

510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92

SUBMITTER INFORMATION	
Name	Biomet Manufacturing Corp.
Address	56 East Bell Drive Warsaw, IN 46582
Phone number	(574) 267-6639
Fax number	(574) 371-1027
Establishment Registration Number	1825034
Name of contact person	Patricia Sandborn Beres Senior Regulatory Specialist Biomet Manufacturing Corp.
Date prepared	March 21, 2013
NAME OF DEVICE	
Trade name	Biomet Reconstructive Wedges
Common name	Wedge
Classification name	Single/multiple component metallic bone fixation appliances and accessories Smooth or threaded metallic bone fixation fastener
Classification panel	Orthopedics
Regulation	21 CFR 888.3030 21 CFR 888.3040
Product Code(s)	HRS HWC
Legally marketed device(s) to which equivalence is claimed	Wright Medical Technology Inc.'s BIOFOAM® Bone Wedges cleared through the following 510(k)s: K070592, K073535 and K093950.
Reason for 510(k) submission	New device
Device description	Biomet Reconstructive Wedges are metallic blocks designed for insertion into voids for alignment of bones in the foot or ankle. There are two styles of wedges which are oval and rectangular in shape. Wedges are available in a variety of widths, lengths and thicknesses. Rectangular cut-out windows allow the surgeon to pack allograft within the device. The wedges are completely porous, to allow for tissue ingrowth. There is a "skin" of solid titanium on the outer edge of the component to facilitate the insertion instrument and allow for identifying part marking to be added to the devices.

Mailing Address:
P.O. Box 587
Warsaw, IN 46581-0587
Toll Free: 800.348.9540
Office: 574.267.6639
Main Fax: 574.267.5137
www.biomet.com

Shipping Address:
56 East Bell Drive
Warsaw, IN 46582

Indications for use	Biomet Reconstructive Wedges are intended to be used for internal bone fixation for bone structures, fusions or osteotomies in the ankle and foot, such as: • Open wedge osteotomies of Hallux Valgus • Evans lengthening osteotomies • Metatarsal/cuneiform arthrodesis Biomet Reconstructive Wedges are intended for use with ancillary fixation. Biomet Reconstructive Wedges are not intended for use in the spine.

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE	
Biomet Reconstructive Wedges uses similar technology to the predicate BIOFOAM® Bone Wedge Devices cleared through 510(k)s K070592, K073535, and K093950. The Biomet Reconstructive Wedges are similar in material, design and sizing to the predicates.	
PERFORMANCE DATA	
Non-Clinical Tests Conducted For Determination Of Substantial Equivalence	
Chemical Composition	Static Shear Strength
Static Compression Testing	Dynamic Compression Testing
Expulsion Testing	Compressive Strength
Porosity/Pore Size	Taber Abrasion
Interconnectivity	Roughness
Tensile Adhesion	MR Compatibility
Microstructure	Animal Data
Clinical Tests Conducted for Determination of Substantial Equivalence and/or of Clinical Information	
No clinical data submitted	
CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA	
No clinical data was necessary for a determination of substantial equivalence. The results of testing indicated the material performed within the intended use, did not raise any new safety and efficacy issues and were found to be substantially equivalent to the predicate devices.	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

March 28, 2013

Biomet Manufacturing Corporation
% Ms. Patricia Sandborn Beres
Senior Regulatory Specialist
56 East Bell Drive
Warsaw, Indiana 46582

Re: K122770
Trade/Device Name: Biomet Reconstructive Wedges
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: February 18, 2013
Received: February 20, 2013

Dear Ms. Beres:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122770

Device Name: Biomet Reconstructive Wedges

Indications For Use:

Biomet Reconstructive Wedges are intended to be used for internal bone fixation for bone structures, fusions or osteotomies in the ankle and foot, such as:

- Open wedge osteotomies of Hallux Valgus
- Evans lengthening osteotomies
- Metatarsal/cuneiform arthrodesis

Biomet Reconstructive Wedges are intended for use with ancillary fixation.

Biomet Reconstructive Wedges are not intended for use in the spine.

Prescription Use ___X___ AND/OR Over-The-Counter Use __NO___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices